REMARKS/ARGUMENTS

By the present amendment, new claims 50 and 51 have been added. Support for new claim 50 is found on page 4, lines 17-19. Support for new claim 51 is found on page 4, lines 25-27. Claims 1, 24 and 36 have been amended to recite that the spectrometer is a Raman spectrometer that operates in the near-infrared range. Support for this amendment is found in claims 2 and 42 (now cancelled) and e.g. on page 7, lines 15-28. Claims 13, 14 and 15 have also been cancelled. Claims 38 and 39 have been amended to delete the term "optical" to accord with the amendments to claim 36 upon which claim 38 is dependent.

The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. The Applicants reserve the right to file any of the canceled subject matter in a divisional patent application. The Applicants submit that no new subject matter has been added by way of the present amendment and entry of the claim amendments is respectfully requested.

The Office Action dated June 29, 2011 and has been carefully considered. It is believed that the claims submitted herewith and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

Claim Rejections 35 U.S.C. § 103(a)

The Examiner rejected claims 1, 3-10, 13-15, 24-26, 36, 38-40 and 47-49 under 35 U.S.C. § 103(a) as being unpatentable over Kanayama (US 20040267139) in view of Rosenfeld et al. (US 20040197930). The Examiner is of the opinion that Kanayama discloses a method and apparatus for sensing the inside of the uterus where the inside of the uterus is continuously monitored by a non-invasive method to detect intrauterine status of oxygenation to predict the risk of developing a medical condition. The Examiner also noted that Kanayama discloses an optical detecting unit for sensing the inside of the uterus using near-infrared light but that "Kanayama does not explicitly teach of a spectrum". The Examiner referred to Rosenfeld et al. as teaching an apparatus and method of analyzing amniotic fluid by creating a spectrum or proteomic profile of biological fluid such that it would have been obvious

to one of ordinary skill in the art to use the teaching of Rosenfeld et al. to modify Kanayama "to provide an effective spectral profile of the fluid to evaluate conditions".

The Examiner also rejected claims 2 and 42 under U.S.C. § 103(a) as being unpatentable over Kanayama and Rosenfeld et al., further in view of Khoury (US 6,618,138. The Examiner stated that Kanayama and Rosenfeld et al. teach the use of a spectrophotometer for measuring the markers but do not teach the use of a Raman spectrometer. The Examiner further stated that Khoury in the same field of endeavor teach the use of a Raman spectrometer such that it would have been obvious to one of skill in the art to use the teaching by Khoury to modify Kanayama and Rosenfeld et al.

Claims 1, 24 and 36 have been amended to refer to a Raman spectrometer that operates in the near-infrared range. Applicants have surprisingly shown that Raman near-infrared spectrometry of amniotic fluid can be used to predict a risk of developing a medical condition in a pregnant mother or her offspring. As set out below, Applicants respectfully submit that none of Kanayama, Rosenfeld et al. nor Khoury, either alone or in combination, teach or suggest the use of Raman near-infrared spectroscopy for analyzing amniotic fluid, nor would the differences between these references and the present invention be considered obvious to a skilled person and therefore cannot be considered to render obvious the claims of the present application.

Kanayama describes an instrument for detecting the intrauterine status of oxygen and in particular the levels of hemoglobin (Hb) and oxygenated hemoglobin (HbO_2). The instrument described in Kanayama relies on the difference in absorption coefficients between Hb and HbO_2 as shown in Figure 2 and measuring the absorption of light at different wavelengths (775 nm, 825 mm, 850 nm and 905 mm) to calculate the changes in concentration of Hb and HbO_2 (see US 20040267139 at paragraphs [0018] to [0024]). Nowhere does Kanayama teach or suggest the use of Raman near-infrared spectroscopy for analyzing amniotic fluid let alone processing spectra to predict a risk of developing a medical condition.

Neither Rosenfeld et al. nor Khoury cure the deficiencies of Kanayama. Rosenfeld et al. describes the proteomic analysis of biological fluids and in particular the identification of proteomic profiles or specific biomarkers using mass spectroscopy or Western blot analysis that are differentially expressed in cases of intra-amniotic infection (IAI) and chromosomal aneuploidies (see paragraphs [0013]-[0027]). Nowhere does Rosenfeld et al. teach or suggest the use of optical spectroscopy, let alone Raman NIR spectroscopy but rather is directed towards mass spectroscopy (see e.g. Figures 4, 14, 15 and paragraphs [0021]-[0023]), which relies on different properties and different instrumentation than Raman NIR spectroscopy.

Applicants submit that a person of skill in the art would not combine the Kanayama and Rosenfeld et al. references to arrive at the claims of the present invention. Kanayama is directed towards an instrument for optically sensing or monitoring the inside of a uterus to determine oxygenation status. In contrast, Rosenfeld et al. describes proteomic methods that involve taking a sample of a biological fluid and analyzing the sample *ex vivo* to generate a proteomic profile in order to diagnose conditions such as IAI and chromosomal aneuploidies (see paragraph [0013]). Rosenfeld et al. define a "proteomic profile" as "a representation of the expression pattern of a plurality of proteins in a biological sample" and refer specifically to techniques such as mass spectra and 2-dimensional polyacrylamide gel electrophoresis (2D PAGE). Kanayama and Rosenfeld et al. are therefore not only directed to different techniques but also to different target analytes. Furthermore, Applicants submit that *even if* a skilled person were to combine the Kanayama and Rosenfeld et al. references they would not arrive at the claims of the present application without the exercise of inventive skill. There is no teaching or suggestion in either Kanayama or Rosenfeld et al. that Raman NIR spectroscopy of amniotic fluid can be used to predict a risk of developing a medical condition nor would a skilled person have a reasonable expectation of success of doing so without the benefit of the disclosure of the present application.

The Examiner stated that Khoury in the same field of endeavor disclose a method for analysis of biological fluids including amniotic fluids and also teach the use of a Raman spectrometer. Khoury describes a "spatial fluorescence spectroscopic association memory-correlator for recognition and classification" (see column 1, lines

57-59) which supposedly can be used in conjunction with a Raman spectrometer (see column 2, lines 46-47). More specifically, Khoury describes a system for *image analysis* as indicated in column 3, lines 24-33:

> "The proposed system of the present invention has enormous performance power compared to any serial based fluorescence correlation spectroscopy system. This is because the proposed system allows the following features to operate simultaneously: (1) scanning line by line; (2) instantaneous spectroscopic correlation of each pixel with hundreds of templates; (3) automatic pixel noise filtering (4) automatic spectrum noise filtering. All these combined features should enable the proposed system to be working as a real time imaging system, in contrast to using the serial scanning approaches that are far slower." (emphasis added)

While Khoury refers to Raman spectroscopy as well as a number of applications of the "system" in pathology, diagnostics or clinical chemistry (see column 2, lines 1 to 19), the teachings of Khoury are directed towards image analysis. Khoury does not provide any data or show any examples of the use of NIR Raman spectroscopy for predicting a risk of developing a medical condition. The Examiner has not shown any teaching, suggestion or motivation that would prompt a skilled person to combine the disparate elements identified in Kanayama, Rosenfeld et al, and Khoury to arrive at the invention as presently claimed. Furthermore, *even if* a skilled person were to combine these elements Applicants submit that a skilled person would not have had any reasonable expectation of success of using a Raman spectrometer that operates in the near-infrared range to predict a risk of developing a medical condition.

In view of the above, the Applicants respectfully request that the Examiner's objections under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

The Applicants respectfully submit that this case is now in condition for allowance and requests that the Examiner's objections be withdrawn and a timely Notice of Allowance be issued. If any additional fees *necessary* to keep the present case pending and/or to protect the filing date are due, or any overpayment has been

made, authorization is hereby given to charge or credit Deposit Account No. 02-2095 for any deficiencies or overages in connection with this response.

The Examiner is requested to contact the undersigned by telephone or e-mail to address any issues that can expedite this case.

Respectfully submitted,

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By: _____

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